

REMARKS

Claims 1-11 and 13-14 remain in this application. Claim 12 has been canceled. New claims 15 and 16 have been added to provide more adequate coverage for applicant's disclosure.

In order to emphasize the patentable distinctions of applicant's invention over the prior art, claim 1 has been amended to recite a surgical sponge comprising a plurality of radiopaque markers, each of said markers having an x-ray density equivalent to at least about 0.1 g/cm² of BaSO₄, wherein said radiopaque markers are disposed in a relationship that is substantially fixed both in spacing and in orientation. These amendments to claim 1 are clearly supported by the original specification. In particular the amendments to claim 1 find support in the specification, as originally filed, at page 15, lines 18-22.

Other amendments to the remaining claims have been effected, for the sake of clarity and consistency, in order to correspond with the amendments to independent claim 1.

In order to provide adequate coverage for applicant's disclosure, new claims 15 and 16 have been added. Claim 15 further limits independent claim 1 by calling for a surgical sponge having a plurality of markers, wherein all of said markers are substantially spherical. Claim 16 further limits independent claim 1 by calling for a surgical sponge having three substantially spherical markers, said markers being closely grouped to one another. New claims 15 and 16 are clearly supported by the original specification. In particular new claims 15 and 16 find support in the specification, as originally filed, at page 15, line 22 to page 16, line 1; page 16, lines 22-24; and Fig. 10.

Applicant's invention provides a surgical sponge comprising a plurality of radiopaque markers having a high radiographic density and a distinctive, visually recognizable shape. The markers have an x-ray density equivalent to at least about 0.1 g/cm² of BaSO₄. The markers produce an x-ray image with high contrast and a shape that is readily recognizable and differentiated from the images produced by other items and structures commonly seen in x-rays of post-operative patients. Owing to the distinctive, high contrast image produced by the markers, the sponge is reliably and unambiguously detected. This is so even in situations where the sponge is inadvertently left in the surgical wound. Discomfort, trauma, and possibly fatal consequences that might otherwise occur are virtually eliminated. The surgical procedure is carried out with decreased likelihood of a sponge being retained inadvertently.

Priority

The Examiner has indicated that applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 111. The Examiner has indicated that provisional application 60/398,040 filed 24 July 2002 has identical claims to the instant application, but there is no reference to that application.

Applicant is in accord with the Examiner's comments regarding priority. A priority claim has not been lodged in the instant application.

Claim Objections

The Examiner has objected to claim 12 because of an informality. Since this claim is being cancelled herein, it is respectfully submitted that the objection to claim 12 has been rendered moot.

Claim Rejections – 35 USC § 103

Claims 1-14 were rejected under 35 USC 103(a) as being unpatentable over Ballard (US 6,777,623 B2).

Regarding claims 1-6, the Examiner has argued that Ballard teaches a surgical sponge (111) comprising a radiopaque marker (301) including barium sulfate (col. 5, lines 10-38). The Examiner has acknowledged that Ballard does not disclose the specific density or size of the marker. However, the Examiner has argued that mere changes in size, weight or shape are not sufficient to patentably distinguish an invention over the prior art. (Citations omitted).

The Examiner has argued that, in the instant case, it is well known in the art that increased density and size of a barium marker increase its ability to be detected by an X-ray. (Citation omitted). The Examiner argues that, at the time of the invention, it would have been obvious to one of ordinary skill in the art to maximize the size and/or density of a barium sulfate marker in a surgical sponge in order to make it more readily detectable by an X-ray.

Applicant respectfully traverses these arguments and submits that the Examiner has not made out a *prima case* of obviousness. Nevertheless, in light

of the present amendments to claims 1-6, applicant submits that present claims 1-6 clearly define over Ballard. Namely, claims 1-6, as amended, call for a surgical sponge comprising a plurality of radiopaque markers, each of said markers having an x-ray density equivalent to at least about 0.1 g/cm² of BaSO₄, wherein said radiopaque markers are disposed in a relationship that is substantially fixed both in spacing and in orientation.

Applicant respectfully submits that nowhere does Ballard disclose or suggest a surgical sponge comprising a plurality of radiopaque markers. Instead, Ballard discloses that each surgical sponge has only one radiopaque object. See claim 23. See also, col. 6, lines 15-30, wherein Ballard discloses that a sensor of the apparatus detects the number of radiopaque objects in the surgical sponges by detecting the scanning beam generated by a radiation source; Ballard further discloses that a computing system calculates the specific number of sponges in the container by counting the number of radiopaque objects.

Furthermore, the Ballard sponge counting device could not be modified to have surgical sponges each comprising a plurality of radiopaque markers without significantly impairing its intended purpose. MPEP 2143.01 states that the proposed modification cannot render the prior art unsatisfactory for its intended purpose, in which case, there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The intended purpose of the apparatus disclosed by the Ballard reference is to be able to count the exact number of surgical sponges that are placed within a container. The Ballard device is intended to count the exact number of surgical

sponges within the container by counting the individual number of radiopaque markers. See Ballard col. 6, lines 15-30. Therefore, in the present case, the Ballard reference does not teach or suggest a device for counting surgical sponges wherein each of the surgical sponges has a plurality of radiopaque markers, as called for by claims 1-6, as amended. Because Ballard requires that each surgical sponge has only one radiopaque marker in order to achieve its intended purpose of counting the exact number of surgical sponges that are placed within a container, it could not be properly modified so that each of the surgical sponges has a plurality of radiopaque markers.

Furthermore, there is no disclosure or suggestion in Ballard for a surgical sponge with a plurality of radiopaque markers, wherein the radiopaque markers are disposed in a relationship that is substantially fixed both in spacing and in orientation. It is submitted that applicant's surgical sponges, as called for by present claims 1-6, are more readily discoverable by a radiologist viewing an X-ray of the patient's body because of there being a plurality of markers disposed in a relationship that is substantially fixed both in spacing and in orientation.

In view of the amendments to present claim 1, and claims 2-6 dependent thereon, it is submitted that claims 1-6 are patentable over Ballard. Accordingly, reconsideration of the rejection of claims 1-6 under 35 U.S.C. § 103(a) as being unpatentable over Ballard is respectfully requested.

Regarding dependent claims 7-11 and 15-16, it is submitted that because these claims depend from independent claim 1, which applicant believes is

patentable over Ballard for the aforementioned reasons, it is submitted that claims 7-11, as amended, and new claims 15-16 are patentable for the same reasons.

Further regarding claim 11, the Examiner states that Ballard teaches that a remotely detectable electronic article tag may be used, such as a radio wave transmitter (col. 5, lines 1-10). The Examiner states that this is one of several which are described as being useful as a marker tag. The Examiner states that although Ballard does not mention simultaneous use of two types of marking technologies in one marker device, both RF transmitting and radiopaque markers are widely used in surgical sponges.

The Examiner argues that, at the time of the invention, it would have been obvious to one of ordinary skill in the art to combine two types of marking technologies in a sponge marker in order to provide for redundant operation. The Examiner argues that if one technology fails to show up on an X-ray, the chances of detecting it are much greater if there is a second, different type of marker.

Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness. In particular, the Examiner has not pointed to any prior art reference that teaches or suggests the claimed combination of the two types of marking technologies, as called for by present claim 11. Instead, applicant submits that such combination is only found by hindsight reasoning and/or applicant's own disclosure. *See* MPEP 2142 *et seq.*

Accordingly, reconsideration of the rejection of claims 7-11 under 35 U.S.C. § 103(a) as being unpatentable over Ballard is respectfully requested.

Regarding claims 13 and 14, the Examiner has argued that it is very well known in the art to incorporate various types of radiopaque markers in surgical sponges for the purpose of determining whether one was left in a patient. The Examiner argues that, because they are radiopaque, it would have been obvious to one of ordinary skill in the art to subject a patient suspected of having an internal sponge (111) to an X-ray, because X-rays readily show any radiopaque material. The Examiner argues, also, the once a sponge has been identified in a patient, it would have been obvious to operate on the patient to remove it before the onset of infection.

It is respectfully submitted that nowhere does Ballard disclose or suggest a method of detecting a surgical sponge within a surgical patient (and treating said surgical patient), said surgical sponge comprising a plurality of radiopaque markers, each of said markers having an x-ray density equivalent to at least about 0.1 g/cm² of BaSO₄, wherein said radiopaque markers are disposed in a relationship that is substantially fixed both in spacing and in orientation. In view of the aforementioned arguments, and the amendments to claims 13 and 14, it is submitted that present claims 13 and 14 patentably define over Ballard.

Accordingly, reconsideration of the rejection of claims 13 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Ballard is respectfully requested.

Regarding new claim 15, it is submitted that nowhere does Ballard disclose or suggest a surgical sponge having a plurality of radiopaque markers,

wherein all of said markers are substantially spherical. Advantageously, this allows for a distinctive, visually recognizable shape in any direction when the sponge is exposed to an X-ray machine, since the imprint of a sphere is the same in any direction. Accordingly, allowance of new claim 15 is respectfully requested.

Regarding new claim 16, it is submitted that nowhere does Ballard disclose or suggest a surgical sponge having three substantially spherical markers, said markers being closely grouped to one another. Advantageously, this configuration allows for a distinctive, visually recognizable shape in any direction when the sponge is exposed to an X-ray machine. The cluster of three substantially spherical markers is readily recognizable in any direction. Accordingly, allowance of new claim 16 is respectfully requested.



CONCLUSION

In view of the amendments to the claims, the amendments to the abstract, and the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Reconsideration of the rejection of claims 1-11 and 13-14, and their allowance, together with new claims 15 and 16, are earnestly solicited.

Respectfully submitted,
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By

A handwritten signature in cursive script, appearing to read "Ernest D. Buff", written over a horizontal line.

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